

510(k) Summary

Submitter Information:

MAY - 8 2012

Primary Contact:

This submission was prepared in April 2012 by:

Suzanne Grenier
Regulatory Affairs Specialist
Terumo Cardiovascular Systems Corporation
125 Blue Ball Road
Elkton, MD 21921
Telephone: 1-800-262-3304, Ext. 7688
Fax: 410-398-6079

Alternate Contact:

Garry A. Courtney, MBA, RAC
Regulatory Affairs Manager
Terumo Cardiovascular Systems Corporation
125 Blue Ball Road
Elkton, MD 21921
Telephone: 1-800-262-3304, Ext. 7486
Fax: 410-398-6079

This submission was prepared for:

Terumo Cardiovascular Systems Corporation
125 Blue Ball Road
Elkton, MD 21921
Registration #1124841

Device Names/Classifications:

<u>Proprietary Name</u>	<u>Classification Name</u>	<u>Common Name</u>
Terumo® Pall AL20X	Cardiopulmonary Bypass	Arterial Filter
Arterial Filter	Arterial Line Blood Filter (Code: DTM)	

Predicate Device(s):

The device submitted in this 510(k) maintains characteristics that are substantially equivalent to the following devices:

- Terumo® Pall AL6X Arterial Filter (K083834)

Intended Use:

The Terumo® Pall AL20X Arterial Filter is indicated for use in cardiopulmonary bypass procedures for the removal of micro-emboli greater than 20 microns in size, including gas emboli, fat emboli, and aggregates composed of platelets, red blood cells, and other debris from the arterial line and where the flow rate will not exceed 7 liters per minute. The device may be used in procedures lasting up to 6 hours in duration.

Principles of Operation and Technology:

The Terumo® Pall AL20X Arterial Filter and the predicate device, Terumo® Pall AL6 Arterial Filter, use the same principles of operation and technology. They perform their functions using two basic forms of technology. As filtration devices, particulates in the blood stream are captured and removed from the blood flow as blood passes through a porous filter material that is contained within the device housing. The filter establishes a physical barrier that entraps particulate matter and prevents it from moving downstream of the arterial filter assembly.

As air-removal devices, the Terumo® Pall AL20X Arterial Filter and the predicate device, Terumo® Pall AL6X Arterial Filter, are designed so that air is removed from the blood stream as a result of centripetal force. The blood inlet port of the device is positioned on the upper-side axis of the polycarbonate housing, thereby creating a spiral blood flow pattern as blood enters the device. As the blood flows through the device in a spiral motion, centripetal forces cause the air bubbles to migrate towards the top of the housing assembly – where air can subsequently be purged from the circuit.

Design and Materials:

The blood-contacting materials that are used in the construction of the Terumo® Pall AL20X Arterial Filter include polycarbonate, polyester, polyurethane, polypropylene, and X-Coating™.

The design differences between the Terumo® Pall AL20X Arterial Filter and the predicate device, Terumo® Pall AL6X Arterial Filter, include filter pore size and maximum flow rate:

Device Characteristics	AL20X	Predicate AL6X
Filter Pore Size	20µm	40µm
Maximum Flow Rate	7 L/min	8 L/min

The Terumo® Pall AL20X Arterial Filter will have a filter pore size of 20 µm while the predicate device, the Terumo® Pall AL6X Arterial Filter, has a filter pore size of 40 µm. Filter pore size of 20 µm to 40 µm for arterial line filters is standard to the industry.¹ The filter pore size dictates the size of micro-emboli such as gas emboli, fat emboli, and aggregates composed of platelets, red blood cells, and other debris that are removed from the fluid flow.

The Terumo® Pall AL20X Arterial Filter will have a maximum flow rate of 7 L/min while the predicate device, the Terumo® Pall AL6X Arterial Filter, has a maximum flow rate of 8 L/min. A blood flow rate of 7 L/min or less is typically used in Cardiopulmonary Bypass procedures – and most bypass components are only qualified to a maximum flow rate of 7 L/min.² For this reason, the difference in flow rates between the modified and current device is not clinically relevant.

Terumo Cardiovascular Systems concludes that the differences between the Terumo® Pall AL20X Arterial Filter and the Terumo® Pall AL6X Arterial Filter do not affect the intended

¹ Cardiopulmonary Bypass: Principles and Practices. Ed. Glenn P Gravlee, et al. – 3rd ed, p93. (Reference included in Appendix A)

² Cardiopulmonary Bypass: Principles and Practices. Ed. Glenn P Gravlee, et al. – 3rd ed, p35. (Reference included in Appendix A)

surgical use of the device nor do they affect safety and effectiveness of the device when used as labeled.

Performance Evaluations:

Terumo Cardiovascular Systems conducted the following *in-vitro* performance evaluations to demonstrate the functional equivalence of the Terumo® Pall AL20X Arterial Filter to the predicate Terumo® Pall AL6X Arterial Filter.

The following tests were performed, and summaries are presented on the ensuing pages:

- Filtration Efficiency
- Air Removal Efficiency
- Effects on Cellular Components
- Effects on Blood Clotting
- Pressure Drop at Various Flow Rates
- Static Priming Volume
- Structural Integrity under Maximum Pressure
- Structural Integrity under Maximum Flow Rate
- Packaging Integrity
- Tubing Connection Strength
- Device Holder Compatibility

Substantial Equivalence Comparison:

In demonstrating substantial equivalence of the Terumo® Pall AL20X Arterial Filter to the predicate Terumo® Pall AL6X Arterial Filter, a comparative study and/or assessment was performed in each of the following areas:

- Intended use
- Target Population
- Duration of use
- Product labeling
- Product design
- Materials used in device construction
- Principles of Operation and Technology
- Device Performance

Substantial Equivalence Statement:

The Terumo® Pall AL20X Arterial Filter is substantially equivalent in intended use, target population, duration of use, labeling, design, materials, principles of operation and technology, and performance to the predicate Terumo® Pall AL6X Arterial Filter device.

Additional Safety Information:

- Sterilization conditions for the Terumo® Pall AL20X Arterial Filter will be validated in accordance with AAMI guidelines to provide a Sterility Assurance Level (SAL) of 10^{-6} . Terumo Cardiovascular Systems further asserts that the ethylene oxide residues will not exceed stated or implied maximum residue limits at the time of product distribution.
- The X-Coating material that is applied to the blood-contacting surfaces of the devices was evaluated in an *in-vivo* animal study conducted by Terumo Cardiovascular and Sierra Biomedical Laboratories in 1999. No adverse conditions were noted.

Conclusion:

Based upon the comparative studies and analyses, Terumo Cardiovascular Systems concludes that the Terumo® Pall AL20X Arterial Filter is *substantially equivalent* to the predicate Terumo® Pall AL6X Arterial Filter device. It is further concluded that any recognized differences noted during the assessments do not raise new issues of patient/user safety or product effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

MAY - 8 2012

Terumo Cardiovascular Systems
c/o Ms. Suzanne Grenier
125 Blue Ball Road
Elkton, MD 21921

Re: K121209

Trade/Device Name: Terumo® Pall AL20X Arterial Filter
Regulation Number: 21 CFR 870.4260
Regulation Name: Arterial Line Blood Filter
Regulatory Class: Class II
Product Code: DTM
Dated: April 19, 2012
Received: April 20, 2012

Dear Ms. Grenier:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

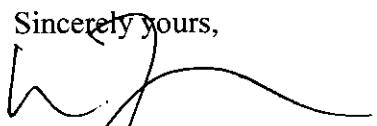
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4
Indications for Use

510(k) Number (if known): K121209

Device Name: Terumo® Pall AL20X Arterial Filter

Indications for Use:

The Terumo® Pall AL20X Arterial Filter is indicated for use in cardiopulmonary bypass procedures for the removal of micro-emboli greater than 20 microns in size, including gas emboli, fat emboli, and aggregates composed of platelets, red blood cells, and other debris from the arterial line and where the flow rate will not exceed 7 liters per minute. The device may be used in procedures lasting up to 6 hours in duration.

Prescription Use XX
(Part 21 CFR 801 Subpart D)

OR
Over-The-Counter Use _____
(Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K121209